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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,066

12/02/2003

Martin Zimmerling

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BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary

Application No.

10/726,066

Applicant(s)

ZIMMERLING ET AL

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-32 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 18, 19 and 31-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 9-17, 20-22, 26 and 29-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 3/05/2007 in which claims 1, 14 and 29 were amended. Currently claims 1-4 and 6-32 are pending for examination in which claims 7-8, 18-19 and 31-32 were withdrawn from a previous election restriction.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 11/07/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 5, 9-10, 12, 14, 16, 20 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis (6,066,088). Davis discloses an intraurethral magnetic valve system.

Regarding claims 1-4, 5, 9-10, 12, 14, 16, 20 and 29-30, Davis discloses a valve (1) for an implantable delivery system (Figure 3) comprising a fluid chamber (1) having a fluid inlet and outlet (near 11, 13) and an internal magnet (14a) disposed within the fluid chamber the internal magnet having a movement axis and a magnetic momentum vector axis, the internal magnet axis and one direction such that the internal magnet is

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movable in two different directions and such that the magnetic momentum vector axis is changed during movement to control fluid flow through the system (Figures 1-2).

Additionally, Davis discloses an external magnet (15a) for rotatable disposition on the skin of a subject for providing a magnetic field for displacing the spherical internal magnet (col 5, ln 40-60) to move the magnet to different flow control positions. The internal magnetic is formed of a biocompatible magnetic material (col 4, ln 35-50) and can be coated (col 4, ln 45-60) with a biocompatible material and is secured within the chamber with anchor members (10, 36) and is capable of being used with a cochlear implant system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis. Davis meets the claim limitations as described above except for the cylindrical internal magnet and the internal magnet coated with silicone.

It would have been an obvious matter of design choice to construct a cylindrical internal magnet, since applicant has not disclosed that a cylindrical solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with spherical magnet.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the internal magnet with the specific silicone coating as claimed by Applicant for biocompatibility, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claim Rejections - 35 USC § 103

Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Erickson (6,966,325). Davis meets the claim limitations as described above except for grooves on a magnetic internal member.

However, Erickson teaches a method and apparatus for a control apparatus.

Regarding claims 13 and 17, Erickson teaches an internal magnetic control member (180) that has a fluid chamber (167) with an inlet and outlet (163, 165) and moveable internal magnetic member (169) with grooves (202) (10B-10C) to allow for fluid movement across the magnetic member (Figures 9A-10C).

At the time of the invention, it would have been obvious to incorporate the grooves of Erickson to the system of Davis in order to enhance flow around the internal magnetic member. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Erickson (cols 2-3).

Claim Rejections - 35 USC § 103

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Rehder et al (USPUBN 2002/01 08623). Davis meets the claim limitation as described above but fails to include an external indicator including a compass.

However, Rehder discloses an external indicator for use with an implantable magnetically actuated device (10) (Figures 1-2).

At the time of the invention, it would have been obvious to incorporate the external indicator of Rehder into the invention of Davis. The motivation would have been in order to locate the device for ease of removal if the device is defective and needs to be replaced (see summary of Rehder).

The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Rehder (see abstract).

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6, 9-17, 20-22, 26 and 29-30. have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

4/28/07


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